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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,713	06/12/2001	Ruedi Aebersold	39-00	5526

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GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/880,713

Applicant(s)

AEBERSOLD ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 53-67, 72 and 73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 and 68-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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**1)** Applicants' election with traverse of Group I, claims 1-52 and 68-71 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that **a)** the kits of Groups II-VI are used for performing the method of Group I and thus are related to Group I and **b)** a search for all of the groups would not pose an undue burden. This traversal is not found persuasive for the following reasons. First, although the kits are disclosed as being useful in the various steps of the labeling method of Group I, a patentability determination for the kits involves an assessment of the novelty and unobviousness of the combination of kit components independent of any method of use (see paragraph **4)b)** of the restriction requirement). Thus, different patentability considerations are involved for an examination of the various kits versus the labeling method of Group I. Second (and related to the first reason), the kits are searched in the technical and patent literature based on the combination of the individual kit components independent of the method of use of the kit while a search of the labeling method is directed to the specific field of labeling phosphopeptides. Thus, the fields of search are not coextensive. It is further noted that the kit of Group VI includes reagents which are not required for the practice of the method of claim 1, e.g. a peptide digesting enzyme and an amine protective group.

Claim 64 (amended) remains as a separate group (Group IV) for the reasons stated in paragraph **4)a)** of the restriction requirement, i.e. Groups II-VI constitute distinct, separately usable subcombinations. The dependency of claim 64 does not affect the basis for the restriction requirement (see, for example, distinct Groups IV-VI which include dependent claims).

Claims 53-67, 72 and 73 are withdrawn from further consideration as being drawn to non-elected inventions. Claims 1-52 and 68-71 are examined on the merits in this Office action.

The requirement is still deemed proper and is therefore made FINAL.

**2)** For future reference, applicants are advised that in accordance with the court decisions in *In re Ochiai*, {71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)} and *In re Brouwer* {77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996)}, in the event that an elected product claim is found to be allowable, a method of

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use claim ***which is of the same scope as the allowed product claim*** may be rejoined with the allowed product claim.

**3)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**4)** Claims 1-52, 70, and 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**a)** For claim 44, there is no description in the specification of a "protecting group" defined as "a hydroxy acid".

**b)** There is no enabling written description in the specification of how to perform the method of claim 22 wherein the phosphate group is not protected prior to its being selectively labeled (as in claim 1, steps b. and c.), i.e. there is no enablement for how to actually perform the method of claim 22 as described at page 7, lines 1-17 and page 10, line 23 *et seq* of the specification. The enabling written description of the invention as set forth in the specification is limited to the method of claim 1 wherein a reagent is used which protects both the carboxylic acid and phosphate groups of the phosphopeptide by the formation of phosphoramidate and amide bonds, followed by the cleavage of the phosphoramidate bond to regenerate free phosphate groups which are then labeled. See Figure 1 and the specification at page 17, line 15 *et seq*. The method described in Example 2 of the specification involves the isotopic labeling of the carboxylic acid groups in the presence of unprotected phosphate groups but does not involve any labeling of the

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phosphate groups per se as is required by claim 22. It is also not clear that the method of claim 1 would work in the absence of a preliminary protection of the amine groups as shown in step 2 of Figure 1 since the unprotected amine would be expected to be affected by the reagents subsequently used in the method.

**5)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

***Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.***

**6)** Claims 1-52 and 68-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** In claim 1 it is unclear what is meant by the term "in the presence of carboxylic acid groups". Are these "carboxylic acid groups" ones which are inherently part of the "peptide" or "protein" to be labeled, or are these additional "carboxylic groups" not related to either the "peptide" or the "protein"?

**b)** In claim 3, there is no antecedent basis in claim 1 for the term "the oligomer or polymer" and it is unclear what is meant by this term.

**c)** In claim 4, there is no antecedent basis in claim 1 for the term "the amino group" and it is unclear what moiety is being referred to. It is also unclear exactly which step of claim 1 is being referred to when the term "reacted with the phosphate group" is used.

**d)** In claim 5, there is no antecedent basis in claim 1 for the term "the solid phase material".

**e)** In claim 7, there is no antecedent basis in claim 1 for the term "the amine protective group".

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**f)** Claim 7 is inconsistent with independent claim 1 for the reason that claim 7 incorrectly implies that the process of claim 1 involves the protection of an amine group. No such step is involved in claim 1.

**g)** Claim 9 is indefinite and incomplete in not reciting a context for the recited reaction. Is the reaction of this claim meant to occur in step c. of claim 1?

**h)** Claim 10 is inconsistent with claim 9 since claim 9 requires the reaction of the "free phosphate groups" with a "linker" while claim 10 requires the reaction of the "free phosphate groups" with "cystamine" (not a "linker").

**i)** In claim 10, it is unclear how the term "a free sulfhydryl group is generated by reduction of cystamine" relates to any of the method steps recited in claim 1.

**j)** In claim 12, there is no antecedent basis in either claim 9 or claim 1 for the term "a solid support material".

**k)** In claim 17, it is unclear what is meant to be included by the term "reactive label".

**l)** In claim 21, there is no antecedent basis in claim 1 for the term "the mixture". It is also unclear how the simple "attachment" or "binding" of the phosphopeptides to a "solid support" or "capture reagent" would result in "separating" the "labeled phosphopeptides".

**m)** In claims 18-21, for example, there is no antecedent basis in claim 1 for the term "phosphopeptides".

**n)** Claim 22 is confusing and indefinite. The claim preamble appears to imply that the method somehow differentially detects specific phosphopeptides; however, there are no method steps recited which would effect any such differentiation.

**o)** The method of claim 23 is inconsistent with the method of claim 22 from which it depends. Claim 22, step a. specifically requires that "any phosphate groups in the peptides remain unprotected" while claim 23 requires the protection of the "phosphate group". See also, claim 24.

**p)** Claim 32 is confusing and inconsistent with claim 22 from which it depends. Since the phosphopeptides of claim 22 are all labeled with "a label", it is unclear if the "selectively labeled peptides"

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are to be somehow separated from each other (method unspecified) or whether they are to be separated from "the sample" (method unspecified).

*q)* It is unclear how the "releasing" step of claim 33 is related to any of the method steps of independent claim 22 which requires only "detecting the peptides carrying the label".

*r)* In claim 37, there is no antecedent basis in claim 1 for the term "two or more samples". There is also no context for determining how the "differentially isotopically labeled carboxylic acid protecting groups are employed". It is unclear whether a different isotope label is used for all phosphopeptides in each sample or for each different type of phosphopeptide in the same sample.

*s)* In claims 41 and 42, there is no antecedent support in claim 1 for the term "the amine group".

*t)* The term "combination of...protecting groups" of claim 43 is inconsistent with the use of "a protective group" in claim 1.

*u)* It is unclear what is meant by the term "hydroxy acid" of claim 44.

*7)* Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

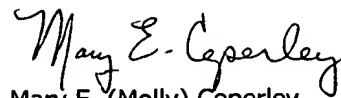
Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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May 02, 2003

A handwritten signature in black ink, reading "Mary E. Ceperley". The signature is written in a cursive, flowing style.

Mary E. (Molly) Ceperley

Primary Examiner

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